REMARKS

The present amendment is in response to the Office action dated 10 November 2008, where the Examiner has rejected claims 1-18. Applicant thanks the examiner for the thorough review of the application as demonstrated by the office action. In the present amendment, claims 1, 5, 8, 14,and 15-18 have been amended and claim 34 has been added. Accordingly, claims 1-18 and 34 are pending in the present application with claims 1 and 34 being the independent claims. Reconsideration and allowance of pending claims 1-18 and 34 in view of the amendments and the following remarks are respectfully requested.

A. Objection to the Specification

The disclosure is objected to for failing to contain headings identifying different sections in accordance with 37 CFR 1.77(b). Applicant believes that the specification is presently in satisfactory form because the present application was filed pursuant to 37 CFR 371, which requires only that a copy of the international application be provided with the national stage application, notwithstanding the differences in the form of the specification between PCT applications and domestic applications. Applicant therefore respectfully requests withdrawal of the objection.

However, if Applicant is incorrect in this belief, a substitute specification will be provided pursuant to a maintained objection to the specification.

B. 35 USC §112

Applicant has amended claims claims 1, 5, 8, 14,and 15-18 pursuant to the suggestions made by the examiner and believes that the 112 rejections are now moot. Withdrawal of the 112 rejection of claims 1-18 is respectfully requested.

However, it is noted that although in amended claim 1 the reference to a porous structure has been placed in the first line for clarity, it is not correct that the first phase must be porous to contain the second phase. It is clear from the specification, e.g. page 2, that the first phase can contain the second phase in a number of ways; for example

the phases may both be particulate or powdered, with the particles of the first phase surrounding the particles of the second phase, or the second phase may be mixed and distributed though the first phase while the first phase is fluid, before allowing the first phase to become solid or semi solid, or the first phase may coat the second phase. The porosity of the overall matrix is a separate requirement; regardless of how the second phase is contained within the first phase, the overall matrix formed from these two phases must still be porous, i.e. have available pores. As indicated at page 9, penultimate paragraph, the pore structure may be formed by gaps between particles of each phase, or by the incomplete liquefaction of the first phase in addition to the inherent porosity of the particles themselves.

C. 35 USC §102(e)

Claims 1, 2, 5-7 and 9-18 stand rejected under section 102(e) as being anticipated by U.S. Patent No. 6,306,169 ("Lee"). Amended claim 1, however, relates to a tissue scaffold wherein the two-phase matrix of the tissue scaffold is porous, i.e. has available pores. In contrast, Lee relates to a tissue implant that is not itself porous – it does not contain available pores. It includes a first matrix component with a porous macrostructure; however in the tissue scaffold product the pores of this component are filled with a second matrix component which is a hydrated alginate gel. Thus in Lee there is not a tissue implant product which is two phase and which overall product is porous. Accordingly, Applicant asserts that amended independent claim 1 is presently in condition for allowance and a notice of allowance for independent claim 1 and its respective dependent claims is respectfully requested.

D. 35 USC §103(a)

Claims 3, 4 and 8 stand rejected under section 103(a) as being unpatentable over Lee in view of U.S. Patent No. 6,534,084 ("Vyakarnam"). As set forth in MPEP § 2143, in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727, 82 USPQ2d 1385, 1395-97 (2007) the Supreme Court identified a number of rationales to

support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The KSR Court noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

However, Vyakarnam does not remedy the deficiencies of Lee. The combination of the teachings of Lee with the teachings of Vyakarnam still does not result in a product according to claim 1 or 34.

Vyakarnam relates to bioabsorbable polymer foams. Particles may be added to a polymer-solvent phase (column 13 line 22) but are not used as the material for forming a matrix. In particular, particles would become encapsulated within a continuous polymer phase, rather than forming a matrix where particles are the actual building blocks.

Further, solvent phase separation uses organic solvents that are toxic in vivo and therefore the teachings of Vyakarnam would not be suitable for producing a scaffold in situ in tissue. Vyakarnam also requires a subsequent solvent extraction process after particles have been added (column 13 line 60 et seq) and again this precludes in situ formation.

There is nothing in Vyakarnam that teaches the skilled artisan that he should produce a tissue scaffold wherein the matrix of the scaffold is two-phase and additionally is porous.

Neither Lee nor Vyakarnam provides the skilled artisan with any teaching towards a beneficial tissue scaffold product in accordance with the invention, which has the advantages of being able to be formed in situ in tissue, can be created from a solidifiable matrix in one single step, can form into the shape of the available cavity, has good diffusion properties and allows drugs, nutrients and other factors to be supplied to the tissue.

Accordingly, Applicant asserts that claims 3, 4 and 8 are presently in condition for allowance and a notice of allowance including claims 3, 4 and 8 is respectfully requested.

E. New Claim 34

New claim 34 is also patentable over Lee and Vyakarnam alone or in combination. Independent claim 34 requires a solidifiable matrix comprising a first phase in a fluid state, and a second phase distributed through the first phase, where the matrix is suitable for introduction into tissue prior to solidification of the first phase to form a porous matrix. In contrast, in Lee the first matrix component is a pre-fabricated porous macrostructure. A solution, which is a precursor of the hydrated gel second matrix component, is infiltrated into these pores and then cross-linked to fill the pores with hydrated gel. Vyakarnam fails to cure the deficiencies of Lee and therefore Applicant believes that independent claim 34 is presently in condition for allowance and a notice of allowance including claim 34 is respectfully requested.

CONCLUSION

For all the foregoing reasons, early allowance of pending claims 1-18 and 34 is respectfully requested. If the Examiner believes that a telephone conversation may be useful in advancing prosecution, the Examiner is invited to contact the undersigned at the number listed below. If necessary, applicant requests to extend the period for filing this reply pursuant to 37 CFR 1.136(a) and authorizes the Director to charge any additional fee(s) or any underpayment of fee(s) or credit any overpayment(s) to Procopio Deposit Account No. 50-2075.

Respectfully submitted,

Dated: 6 January 2009

By: /Pattric J. Rawlins/
Pattric J. Rawlins
Reg. No. 47,887
(619) 238-1900